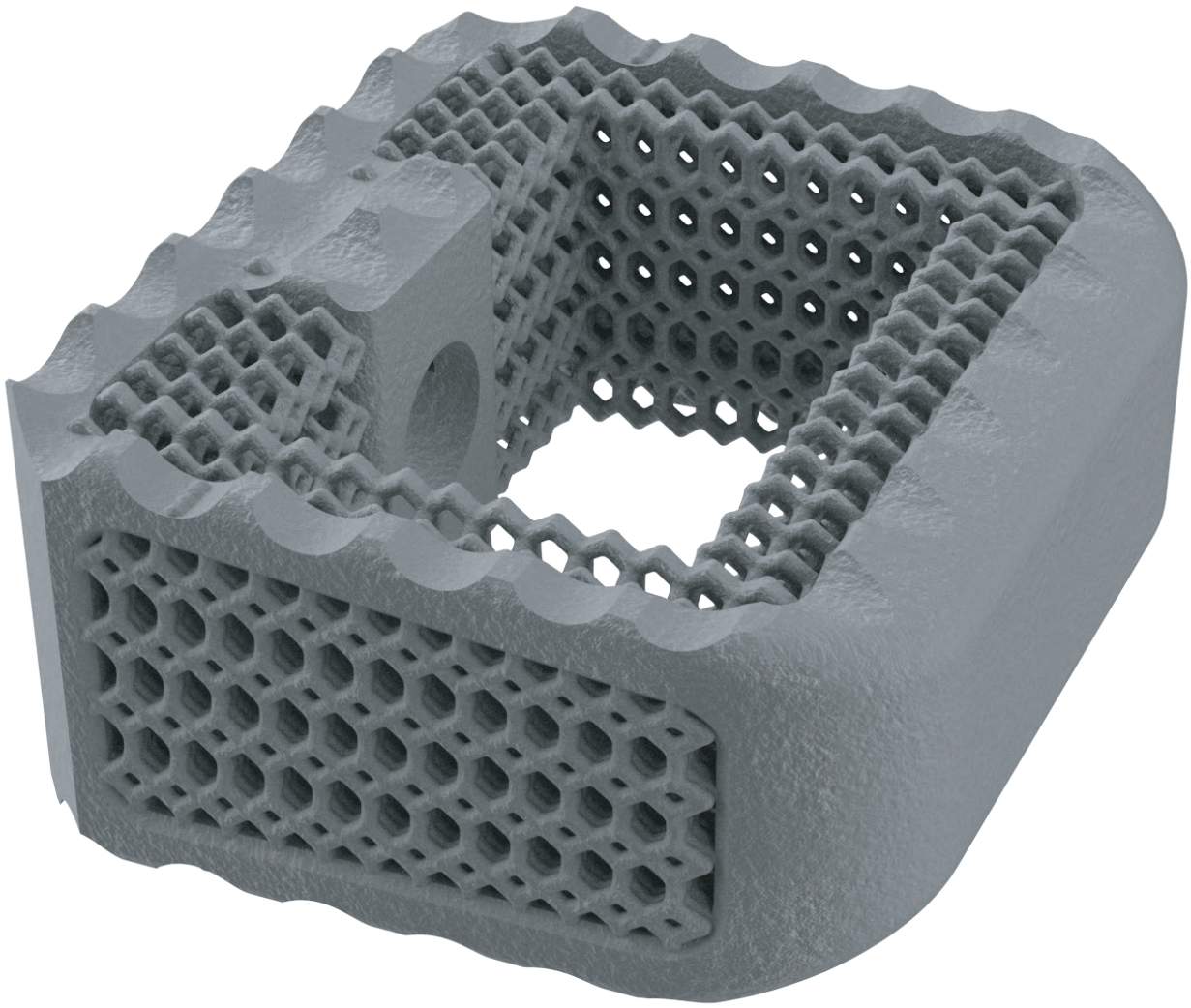
NEXXT MATRIXX®

Cervical Interbody



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Caution: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

PATIENT POSITIONING

Following adequate general anesthesia, the patient is placed in the supine position with the head in slight extension (Fig. 1). The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis.

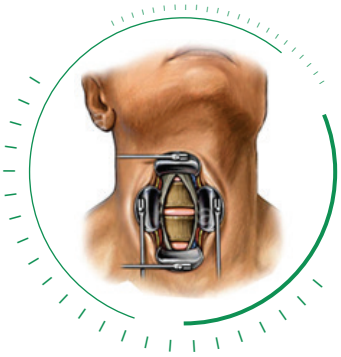


Figure 1

EXPOSURE OF OPERATIVE LEVEL(S)

Access the operative site and retract the tissues using preferred instruments. Retract the muscles, trachea, esophagus and carotid artery to clearly see the vertebral bodies and discs. Insert a marker into the disc(s) and confirm the correct operative level(s) using a lateral radiograph (Fig. 2).

NOTE: Nexxt Matrixx® Cervical Interbodies are indicated for use at up to two contiguous levels in the cervical spine from C2-T1.

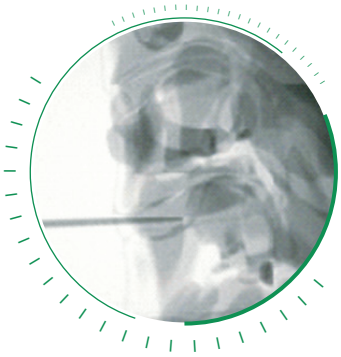


Figure 2

DISCECTOMY

Perform a complete discectomy using preferred surgical instruments. Pituitaries, curettes, and rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament and endplates. A high-speed burr may be used for removal of posterior osteophytes to achieve neural decompression (Fig. 3). The posterior longitudinal ligament may be removed to access and remove any disc material that may be pressing on the neural elements.

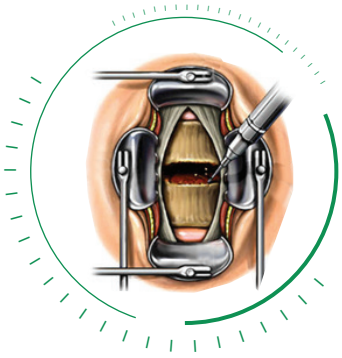
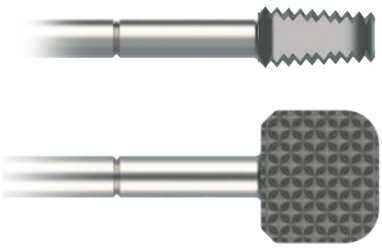


Figure 3

NOTE: Adequate preparation of the endplates is critical in facilitating vascular supply to promote fusion.
WARNING: Excessive removal of subchondral bone during endplate preparation may weaken the bone, resulting in subsidence and/or segmental instability.

ENDPLATE PREPARATION

Rasps can be used sequentially, in 1mm increments, to remove the superficial layer on the endplates (Fig. 4). This will aid in creating bleeding bone to promote spinal fusion. Appropriate endplate preparation will optimize surface contact with the selected interbody.



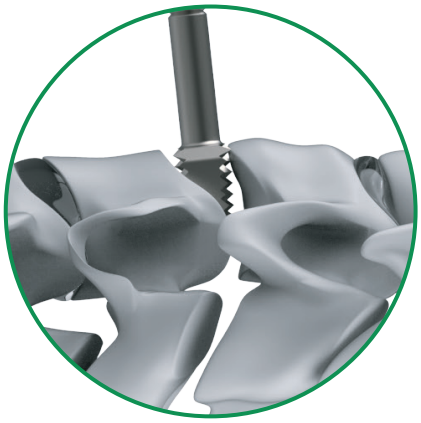
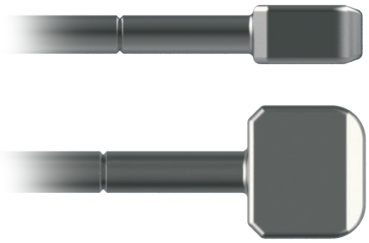


Figure 4

IMPLANT SIZE SELECTION

Selection of the Trial depends on the height, width, and depth of the intervertebral space. Based on pre-operative imaging and surgical technique, select a Trial of appropriate height (Fig. 5).

Each Trial is color coded to differentiate height and should be used incrementally to determine the appropriate dimensions of the interbody required (Fig. 6).



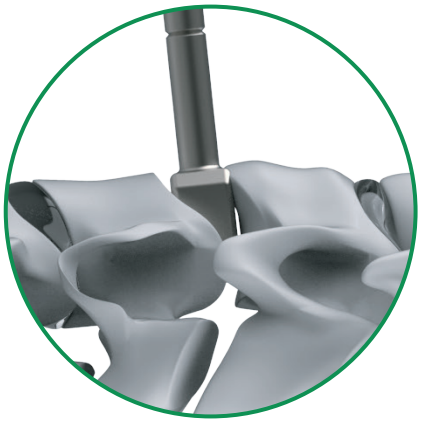


Figure 5

NOTES:

-Rasp and Trial sizes (w x d x h) are a line-to-line match to the corresponding interbody.

-Standard Angulation (Lordosis) of Rasps, Trials and corresponding interbodies is 6°. 0° versions are optional.

-All labeled heights are measured from the area representing the highest point on the anterior wall of the implant.

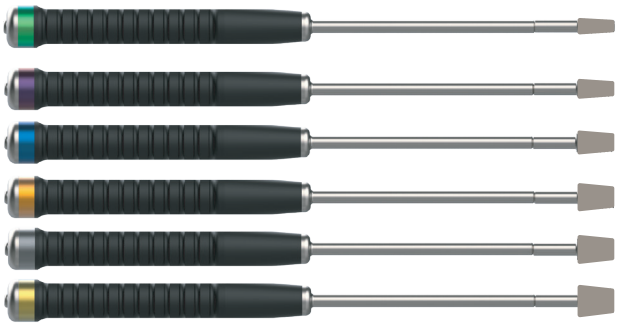


Figure 6

IMPLANT PREPARATION AND INSERTION

Open the sterile packaging of the Interbody (height and footprint) that was determined with the Trial. There is no need to undersize or oversize the Implant.

Attach the Interbody to the Inserter by aligning the male/female thread components while rotating the instrument handle clockwise. Confirm the Implant is securely attached but DO NOT overtighten (Fig. 7).

If desired, a modular sleeve with a 2mm Safety Stop can be attached to the shaft of the Inserter prior to loading the implant. The Safety Stop will contact the anterior edge of the vertebral body when the Interbody is inserted 2mm beyond the anterior edge of the vertebral body.

Adjust the position of the Safety Stop on the modular Inserter sleeve if utilized. Safety stop should be positioned in the cephalad orientation.

Pack the center cavity of the Implant with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft (Fig. 8).

Gently insert the Implant into the intervertebral disc space. It is important to ensure the Implant is seated in the midline of the disc space and slightly recessed (approximately 2mm). If necessary, controlled and light tamping with a mallet can be used to help advance the implant to the desired position within the intervertebral disc space.

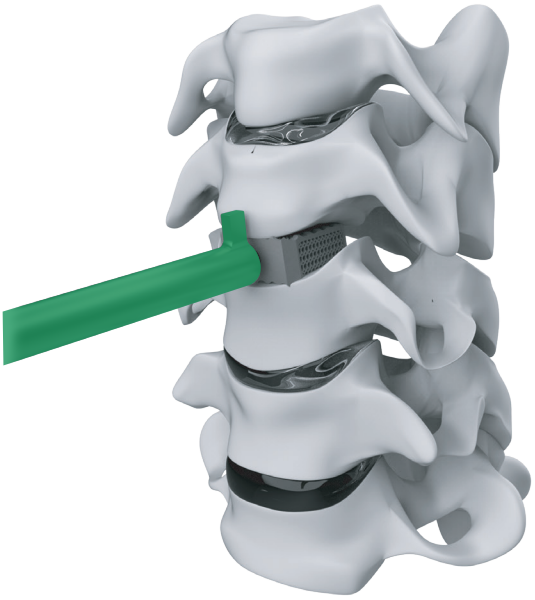


Figure 7

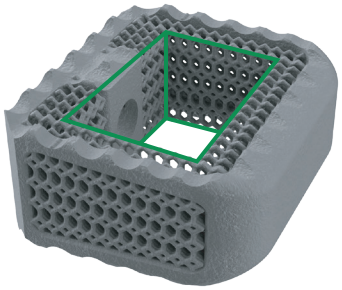


Figure 8

NOTES:

-Use caution when tightening the Implant to the Inserter to avoid stripping threads or overtightening where detachment of implant from instrument becomes difficult.

-Standard implants have a 6° angle of lordosis. 0° versions are offered as optional.

-Implant heights are measured from the area representing the highest point on the anterior wall of the implant.

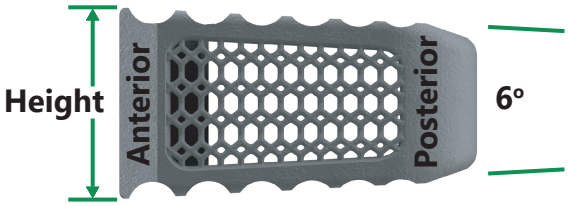


Figure 9

IMPLANT PREPARATION AND INSERTION (CONT.)

The use of fluoroscopy is recommended during any or all of the implantation steps to ensure proper positioning (Fig. 11).

Rotate the Inserter handle in a counterclockwise direction to release the implant from the Inserter.

If the implant requires further adjustment, use the Cervial Tamp to carefully manipulate the implant into desired position.

Complete the procedure by following the surgical technique for the specific device to be used as supplemental fixation, such as the Nexxt Spine Struxxure® Anterior Cervical Plate System.

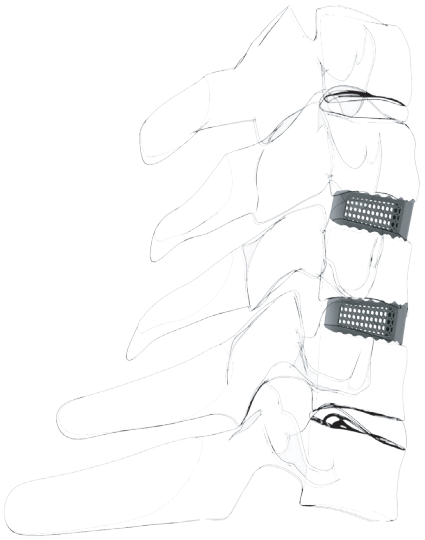


Figure 11

IMPLANT REMOVAL

Either the Inserter or Universal Removal Instrument may be used for Implant removal by attachment via clockwise rotation to the implant threads (Fig. 12). Be careful to avoid pushing the implant posteriorly. Once the implant is firmly attached, remove the implant from the disc space.

Vertebral bone overgrowth or osteophytes may be removed to facilitate implant retrieval.

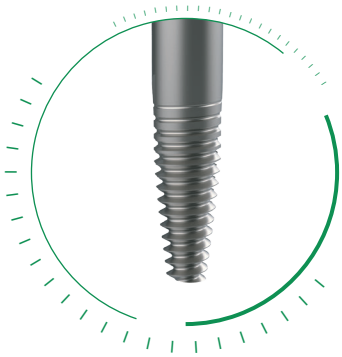


Figure 12

DEVICE DESCRIPTION

Nexxt Matrixx® is a collection of additively manufactured spacers for cervical, lumbar/lumbosacral and thoracolumbar implantation. The basic shape of these implants is a structural column to provide surgical stabilization of the spine. Each device comprises an external structural frame having a roughened surface (~7µm). The intervening geometric lattices have pores 300-700µm. The inferior/superior aspects of the Nexxt Matrixx® open devices incorporate a large vertical cavity which can be packed with bone graft material. The inferior/superior aspects of the Nexxt Matrixx® solid devices are closed and do not permit the packing of bone graft within the implant. The solid devices are only to be used for partial vertebral body replacement. The open and solid devices are available in an assortment of height, length, width and lordotic angulation combinations to accommodate the individual anatomic and clinical circumstances of each patient. The Nexxt Matrixx® implants are manufactured from Titanium Alloy (Ti6Al4V) as described by ASTM F3001.

INDICATIONS

When used as a cervical intervertebral fusion device, the Nexxt Matrixx® System open devices are indicated for use at up to two contiguous levels in the cervical spine, from C2-T1, in skeletally mature patients who have had six weeks of non-operative treatment for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and with supplemental fixation.

CONTRAINDICATIONS

Nexxt Matrixx® contraindications include, but are not limited to:

1. The presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, any demonstrated allergy or foreign body sensitivity to any of the implant materials, drugs/alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. Any condition not described in the Indications for Use.
4. Prior fusion at the level(s) to be treated.

WARNINGS AND PRECAUTIONS

1. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
2. Nexxt Matrixx® devices should be implanted only by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for use of these devices.
3. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
4. Nexxt Matrixx® solid devices are not intended for interbody fusion as bone growth through the device has not been demonstrated.
5. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition.
6. Nexxt Matrixx® is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
7. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
9. Components of this system should not be used with components of any other system or manufacturer.
10. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

NEXXT MATRIXX® IMPLANT PRODUCT NUMBERS

NEXXT MATRIXX® CERVICAL

Standard P/N	Description
50M-1214-05-SP	Cervical 12D x 14W x 5H
50M-1214-06-SP	Cervical 12D x 14W x 6H
50M-1214-07-SP	Cervical 12D x 14W x 7H
50M-1214-08-SP	Cervical 12D x 14W x 8H
50M-1214-09-SP	Cervical 12D x 14W x 9H
50M-1214-10-SP	Cervical 12D x 14W x 10H
50M-1212-XX-SP*	Cervical 12D x 12W x 5-18H
50M-1212P-XX-SP*	Cervical Parallel 12D x 12W x 5-18H
50M-1214-XX-SP*	Cervical 12D x 14W x 11-18H
50M-1214P-XX-SP*	Cervical Parallel 12D x 14W x 5-18H
50M-1416-XX-SP*	Cervical 14D x 16W x 5-18H
50M-1416P-XX-SP*	Cervical Parallel 14D x 16W x 5-18H
50M-1618-XX-SP*	CIB, 16D x 18W x 5-18H

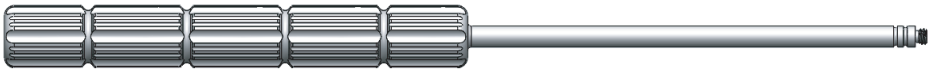
*Optional

NEXXT MATRIXX® INSTRUMENT PRODUCT NUMBERS

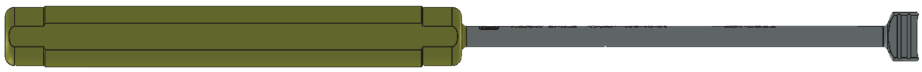
I35-10M-XX Cervical, Trial, 6° (0°*), 12x14xXXmm (12x12xXX*, 14x16xXX*, 16x18xXX*)

I35-20M-XX Cervical, Rasp, 6°, 12x14xXXmm (12x12xXX*, 14x16xXX*, 16x18xXX*)

I50-01-01 Cervical, Inserter



I35-40-01 Cervical, Tamp



I35-50-01S Universal Remover, Short

I35-31-01 Cervical, Inserter Sleeve*

*Optional

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